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EVALUATION OF ACCURACY OF SYNOVIAL FLUID LEUKOCYTE ESTERASE IN DIAGNOSING SEPTIC ARTHRITIS

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ABSTRACT

Background: Septic arthritis is an orthopedic emergency requiring rapid diagnosis to prevent irreversible joint damage. Synovial fluid leukocyte esterase (LE) dipstick testing is a rapid bedside alternative to conventional culture.

Objective: To evaluate the diagnostic accuracy of synovial fluid leukocyte esterase for diagnosing bacterial septic arthritis and compare its performance with synovial fluid culture.

Materials and Methods: This hospital-based cross-sectional observational study included 65 adults with clinically suspected bacterial septic arthritis. Synovial fluid samples underwent LE dipstick testing and microbiological culture. Dipstick readings of 2+ and 3+ were considered positive. Diagnostic performance was assessed using sensitivity, specificity, predictive values, accuracy, odds ratio, and ROC analysis.

Results: Of the 65 patients, 40 (61.5%) were diagnosed with bacterial septic arthritis. Leukocyte esterase positivity was observed in 52 (80.0%) patients and showed a significant association with bacterial septic arthritis (95.0% vs. 56.0%; p=0.000225). Positive LE was identified as the strongest independent predictor of septic arthritis (OR=14.9, 95% CI: 2.8–78.5; p=0.0002). Using synovial fluid culture as the reference standard, LE demonstrated a sensitivity of 94.7%, specificity of 26.1%, PPV of 34.6%, NPV of 92.3%, and accuracy of 46.2%. Against the diagnosis of bacterial septic arthritis, sensitivity, specificity, PPV, NPV, and accuracy were 95.0%, 44.0%, 73.1%, 84.6%, and 75.4%, respectively. ROC analysis yielded an AUC of 0.78.

Conclusion: Synovial fluid leukocyte esterase is a rapid, inexpensive, and highly sensitive bedside screening test that can support early diagnosis and timely management of bacterial septic arthritis while awaiting culture confirmation.

KEYWORDS: Septic arthritis, Leukocyte esterase, Synovial fluid, Diagnostic accuracy, Sensitivity, Specificity.

INTRODUCTION

Septic arthritis (SA) is an orthopedic emergency characterized by bacterial infection of the synovial joint, resulting in rapid cartilage destruction, severe inflammation, and irreversible loss of joint function if diagnosis and treatment are delayed.[1] The synovial membrane lacks a limiting basement membrane, allowing microorganisms to enter the joint space easily and proliferate rapidly. Once infection is established, an intense inflammatory response is triggered, leading to neutrophil recruitment, release of proteolytic enzymes, and progressive destruction of articular cartilage.[2,3] Because joint damage can occur within a short period after infection, early diagnosis and prompt initiation of appropriate therapy are critical to preserving joint integrity and preventing long-term disability.[4]

Septic arthritis can affect individuals of all age groups, although its incidence is higher among children, elderly individuals, and patients with underlying comorbidities. The reported annual incidence of native joint septic arthritis ranges from 2 to 10 cases per 100,000 population worldwide.[5–7] Risk factors include diabetes mellitus, chronic kidney disease, rheumatoid arthritis, malignancy, immunosuppressive conditions, pre-existing joint disorders, and invasive procedures involving the joint.[8] The knee is the most commonly affected joint in adults, whereas both the hip and knee are frequently involved in children. Despite improvements in antimicrobial therapy and surgical management, septic arthritis remains associated with considerable morbidity, functional impairment, repeated surgical interventions, and mortality rates ranging from 5% to 15%.[9,10]

In India, septic arthritis continues to pose a significant clinical burden due to delayed presentation, limited access to specialized healthcare facilities, empirical antibiotic administration before diagnostic sampling, and variability in laboratory diagnostic capabilities.[11] Moreover, several conditions such as crystal arthropathies, inflammatory arthritis, reactive arthritis, and hemarthrosis can mimic septic arthritis clinically, making accurate diagnosis difficult. Consequently, a reliable and rapid diagnostic method is essential to facilitate early treatment decisions and improve patient outcomes.[12,13]

Although synovial fluid culture remains the gold standard for diagnosis, its major limitation is the delay of 24–72 hours required for microbial growth and identification. Furthermore, prior antibiotic exposure may reduce culture positivity.[14,15] Other investigations, including Gram stain, synovial leukocyte count, ESR, and C-reactive

protein, provide supportive evidence but lack sufficient sensitivity or specificity to definitively confirm or exclude infection.[16] Therefore, there is growing interest in rapid point-of-care biomarkers that can aid clinical decision-making while awaiting definitive microbiological results.

Leukocyte esterase (LE) is an enzyme released by activated neutrophils and has long been used in urine dipstick testing as an indicator of pyuria. Since bacterial septic arthritis is characterized by intense neutrophilic infiltration within the synovial fluid, LE dipstick testing has emerged as a promising bedside diagnostic tool.[17,18] The test is inexpensive, readily available, easy to perform, and provides results within minutes. Given the need for rapid diagnosis in septic arthritis, evaluation of synovial fluid leukocyte esterase may offer an effective screening method for early identification of bacterial joint infection.[19] Therefore, the present study was undertaken to evaluate the accuracy of synovial fluid leukocyte esterase in diagnosing bacterial septic arthritis and to compare its performance with synovial fluid culture as the reference standard.

MATERIALS AND METHODS

The present hospital-based cross-sectional observational study was conducted at Teerthanker Mahaveer Medical College and Research Centre (TMMC&RC), Moradabad, Uttar Pradesh, in collaboration with the Departments of Orthopaedics, Pathology, and Microbiology. The study was carried out during the academic period from 2023 to 2026 after obtaining approval from the College Research Committee and Institutional Ethics Committee.

Adult patients presenting with clinical suspicion of bacterial septic arthritis in the outpatient or inpatient services of the Department of Orthopaedics were considered eligible for inclusion. Clinical suspicion was based on the presence of acute onset joint pain, fever, inability to bear weight, limping, severe pain on passive movement, or joint pseudoparalysis. Patients providing written informed consent were enrolled in the study. Cases with inadequate synovial fluid samples (<2 mL), delayed sample processing (>2 hours), hemorrhagic aspirates, or a definite history of antibiotic intake within the preceding seven days were excluded.

A sequential sampling technique was adopted, and all eligible patients were included until the required sample size was achieved. Synovial fluid aspiration was performed under strict aseptic precautions by the treating orthopaedic surgeon. The aspirated sample was divided into two aliquots. One aliquot was sent to the Clinical Pathology Laboratory for routine examination and microscopic analysis, while the other was processed in the Microbiology Laboratory for culture and bacterial identification. All samples were transported and analyzed within two hours of collection.

Leukocyte esterase testing was performed using the B10 Orinasys 10SG reagent strip. The strip was immersed in freshly aspirated synovial fluid and interpreted after 120 seconds according to the manufacturer's instructions. For analysis, dipstick readings of 2+ and 3+ were considered positive, whereas negative, trace, and 1+ readings were considered negative.

Synovial fluid culture was performed using standard microbiological techniques and served as the reference standard for diagnosis. Clinical details, leukocyte esterase results, and culture findings were recorded in a predesigned proforma. The primary outcome measure was the diagnostic accuracy of synovial fluid leukocyte esterase for detecting bacterial septic arthritis.

Sample Size Calculation

The sample size was calculated using the formula: $n = Z^2\alpha/_2 \times P\ (100 - P) / E^2$, where $Z^2\alpha/_2$ represents the standard normal deviation at 95% confidence interval (1.96), P represents the expected specificity of synovial fluid leukocyte esterase (80.8%), and E represents the allowable error (10%). Substituting these values into the formula: $n = (1.96)^2 \times 80.8 \times (100 - 80.8) / 10^2 = 3.8416 \times 80.8 \times 19.2 / 100 = 59.6$. Therefore, the minimum required sample size for the study was approximately 61 patients.

Statistical Analysis

Data were entered into Microsoft Excel and analyzed using IBM SPSS Statistics version 26. Continuous variables were expressed as mean ± standard deviation, while categorical variables were presented as frequencies and percentages. Associations between categorical variables were assessed using the Chi-square test or Fisher's Exact test, as appropriate. Diagnostic performance of synovial fluid leukocyte esterase was evaluated by calculating sensitivity, specificity, positive predictive value, negative predictive value, accuracy, and 95% confidence intervals. A p-value <0.05 was considered statistically significant.

RESULTS

A total of 65 patients with clinical suspicion of bacterial septic arthritis were enrolled in the present study. The baseline demographic and clinical characteristics of the study population are presented in **Table 1**. The mean age of the participants was 45.60 ± 16.51 years, with the majority of patients (55.4%) belonging to the 18–45-year age group. Patients aged more than 60 years accounted for 26.2% of the study population, while the remaining participants were between 46 and 60 years of age. Females constituted 58.5% of the study population, whereas males represented 41.5%. Regarding joint involvement, the knee was the most commonly affected joint, accounting for 64.6% of cases, followed by the hip in 35.4% of patients. A history of trauma was reported in 26.2% of participants, while recent surgery was documented in 13.8% of cases (**Table 1**).

Table 1. Baseline Demographic and Clinical Characteristics of Study Participants

Variable	Frequency (n)	Percentage (%)
Age Group (Years)		
18–45	36	55.4
46–60	12	18.5
>60	17	26.2
Gender		
Female	38	58.5
Male	27	41.5
Joint Involved		
Knee	42	64.6
Hip	23	35.4
History of Trauma		
Yes	17	26.2
No	48	73.8
Recent Surgery		
Yes	9	13.8
No	56	86.2

The synovial fluid characteristics and diagnostic findings are summarized in **Table 2**. Among the collected synovial fluid samples, 52.3% were turbid, 36.9% were purulent, and 10.8% appeared clear on gross examination. Leukocyte esterase testing was positive in 52 patients (80.0%), whereas synovial fluid culture was positive in only 19 patients (29.2%). Based on the final clinical diagnosis, 40 patients (61.5%) were diagnosed with bacterial septic arthritis and 25 (38.5%) with non-septic arthritis. The distribution of final diagnoses is illustrated in **Figure 1**, demonstrating that bacterial septic arthritis constituted the predominant diagnosis in the study population.

Table 2. Synovial Fluid Characteristics and Diagnostic Findings

Variable	Frequency (n)	Percentage (%)
Synovial Fluid Appearance		
Clear	7	10.8
Purulent	24	36.9
Turbid	34	52.3
Leukocyte Esterase Test		
Positive	52	80
Negative	13	20
Synovial Fluid Culture		
Positive	19	29.2
Negative	46	70.8
Final Diagnosis		
Bacterial Septic Arthritis	40	61.5
Non-septic Arthritis	25	38.5

The association between leukocyte esterase positivity and final diagnosis is presented in **Table 3**. A significant association was observed between leukocyte esterase findings and bacterial septic arthritis (95.0% vs 56.0%; p=0.000225). In contrast, age group, gender, affected joint, history of trauma, recent surgery, and synovial fluid appearance were not significantly associated with the final diagnosis (p>0.05). These findings indicate that leukocyte esterase positivity was strongly related to the presence of bacterial septic arthritis.

Table 3. Association Between Leukocyte Esterase Findings and Final Diagnosis

Leukocyte Esterase	Bacterial Septic Arthritis (n=40)	Non-septic Arthritis (n=25)	p-value
Positive	38 (95.0%)	14 (56.0%)	
Negative	2 (5.0%)	11 (44.0%)	**0.000225**

The independent association between clinical variables and bacterial septic arthritis was further evaluated using odds ratio analysis (**Table 4**). Positive leukocyte esterase was identified as the strongest predictor of bacterial septic arthritis, with patients demonstrating 14.9-fold higher odds of disease compared with those having negative test results (adjusted OR = 14.9, 95% CI: 2.8–78.5; p = 0.0002). Although culture positivity showed a trend toward increased odds of septic arthritis (adjusted OR = 3.2, p = 0.064), the association did not reach statistical significance. Similarly, history of trauma (adjusted OR = 1.7, p = 0.372) and recent surgery (adjusted OR = 0.8, p = 0.480) were not significantly associated with bacterial septic arthritis. These findings indicate that synovial fluid leukocyte esterase positivity was the only independent predictor significantly associated with the diagnosis of bacterial septic arthritis in the present study.

Table 4. Odds Ratio Analysis for Predictors of Bacterial Septic Arthritis

Variable	Adjusted OR	95% CI	p-value
Positive Leukocyte Esterase	14.9	2.8–78.5	0.0002
Culture Positivity	3.2	0.9–11.4	0.064
History of Trauma	1.7	0.5–5.8	0.372
Recent Surgery	0.8	0.2–3.4	0.48

The diagnostic performance of synovial fluid leukocyte esterase is presented in **Tables 5 and 6**. Using synovial fluid culture as the reference standard, leukocyte esterase correctly identified **18 of 19 culture-positive cases**, yielding a sensitivity of **94.7%**, specificity of **26.1%**, positive predictive value (PPV) of **34.6%**, negative predictive value (NPV) of **92.3%**, and overall accuracy of **46.2%**. When evaluated against the diagnosis of bacterial septic arthritis, the test correctly identified **38 of 40 septic arthritis cases**, resulting in a sensitivity of **95.0%**, specificity of **44.0%**, PPV of **73.1%**, NPV of **84.6%**, and overall accuracy of **75.4%**. The consistently high sensitivity and NPV observed in both analyses indicate that synovial fluid leukocyte esterase is a reliable screening test with a strong ability to identify bacterial septic arthritis and effectively exclude disease when the test result is negative

Table 5. Diagnostic Accuracy of Synovial Fluid Leukocyte Esterase Compared with Synovial Fluid Culture

Diagnostic Accuracy	Total Cases(n)	Concordant Cases (n)	Percentage (%)	95% Confidence Interval (%)
Sensitivity	19	18	94.7	84.7–100.0
Specificity	46	12	26.1	13.4–38.8
PPV	52	18	34.6	21.7–47.5
NPV	13	12	92.3	77.8–100.0
Accuracy	65	30	46.2	34.0–58.3

Table 6. Diagnostic Performance of Synovial Fluid Leukocyte Esterase for Diagnosis of Bacterial Septic Arthritis

Diagnostic Accuracy	Total Cases(n)	Concordant Cases (n)	Percentage (%)	95% Confidence Interval (%)

Sensitivity	40	38	95.0	88.2–100.0
Specificity	25	11	44.0	24.5–63.5
PPV	52	38	73.1	61.0–85.1
NPV	13	11	84.6	65.0–100.0
Accuracy	65	49	75.4	64.9–85.9

Receiver operating characteristic (ROC) analysis (**Figure 3**) demonstrated an area under the curve (AUC) of 0.78 (95% CI: 0.66–0.90; p<0.001), indicating acceptable diagnostic accuracy for differentiating bacterial septic arthritis from non-septic arthritis. Collectively, the findings from **Tables 3–6** and **Figures 2–3** support the utility of synovial fluid leukocyte esterase as a rapid, inexpensive, and highly sensitive bedside screening test for the early diagnosis of bacterial septic arthritis.

DISCUSSION

The present study evaluated the diagnostic utility of synovial fluid leukocyte esterase (LE) in patients with clinical suspicion of bacterial septic arthritis and demonstrated a significant association between LE positivity and disease diagnosis. Among the 65 enrolled patients, bacterial septic arthritis accounted for 61.5% of cases, reflecting the high pre-test probability of infection in patients selected on clinical grounds. A notable finding of the study was that 80.0% of synovial fluid samples were LE positive, whereas only 29.2% yielded positive culture results. This discrepancy highlights a well-recognized limitation of synovial fluid culture, which may be affected by low bacterial load, prior antibiotic exposure, and technical factors. Recent reviews have similarly emphasized that culture-negative septic arthritis remains a significant diagnostic challenge and that rapid biomarker-based approaches may improve early detection of infection.

The strongest finding of the present study was the highly significant association between LE positivity and bacterial septic arthritis. LE was positive in 95.0% of patients with septic arthritis compared with only 56.0% of patients with non-septic arthritis (p=0.000225). Furthermore, multivariable analysis identified positive LE as the only independent predictor of septic arthritis, increasing the odds of disease by nearly fifteen-fold (OR=14.9, 95% CI: 2.8–78.5; p=0.0002). Such a strong association supports the biological basis of LE testing, as bacterial joint infection induces intense neutrophilic infiltration of synovial fluid, resulting in increased release of leukocyte esterase enzyme. Similar observations were reported by Mirghaderi et al.[20], who found a highly significant association between positive LE reactions and septic arthritis, while Dey et al. reported LE as the best-performing synovial biomarker with a pooled sensitivity of 94% in their systematic review.

Diagnostic accuracy analysis further demonstrated that LE possesses excellent screening performance. When culture was used as the reference standard, LE correctly identified 18 of 19 culture-positive cases, resulting in a sensitivity of 94.7%. Importantly, sensitivity remained almost identical (95.0%) when evaluated against the diagnosis of bacterial septic arthritis. These findings are remarkably consistent with those reported by Kolbeck et al.[21] (95%), Mortazavi et al.[20] (100%), Colvin et al.[18] (100%), and Chen et al.[22] (87%), confirming that LE is highly effective in identifying infected joints. The consistency of high sensitivity across different populations, age groups, and study designs suggests that LE testing has robust diagnostic performance irrespective of clinical setting.

The negative predictive value observed in the present study was also noteworthy. An NPV of 92.3% against culture and 84.6% against bacterial septic arthritis indicates that a negative LE result substantially reduces the probability of infection. Similar NPVs have been reported by Gautam et al.[23] (90.1%), Hassas Yeganeh et al.[24] (86.8%), Mortazavi et al.[20] (100%), and Colvin et al.[25] (100%). From a clinical perspective, this high NPV is particularly important because septic arthritis is a disease in which missed diagnosis can result in irreversible cartilage destruction and permanent disability. Therefore, the ability of LE testing to reliably exclude infection has considerable practical value in emergency and orthopedic settings.

Although sensitivity was excellent, specificity was comparatively lower in the present study (26.1% against culture and 44.0% against diagnosis) than in many previous reports. Meta-analyses by Chen et al.[22] reported pooled specificities of approximately 96%, while Gautam et al.[23] and Hassas Yeganeh et al.[24] reported specificities of 80.8% and 78.6%, respectively. The lower specificity observed in our study may be attributable to the inclusion of patients with inflammatory joint disorders, where neutrophilic inflammation can also produce positive LE reactions. This interpretation is supported by studies demonstrating that specificity improves substantially when higher positivity thresholds are applied or when LE is combined with additional biomarkers such as glucose or alpha-defensin. Therefore, while LE is highly valuable as a screening tool, positive results should be interpreted within the broader clinical context.

Another important finding was the overall diagnostic accuracy of 75.4% and an ROC-AUC of 0.78, indicating

acceptable discriminatory ability. Comparable AUC values have been reported by Grünwald et al.[26] (0.82) and Yu et al.[27] (0.85), supporting the reliability of LE testing as a diagnostic adjunct. Considering its low cost, immediate availability, minimal technical requirements, and rapid turnaround time, LE testing offers significant advantages over advanced molecular and immunological biomarkers, particularly in resource-limited healthcare settings.

CONCLUSION

Synovial fluid leukocyte esterase is a rapid, inexpensive, and highly sensitive bedside test for the diagnosis of bacterial septic arthritis. The test demonstrated excellent sensitivity (95.0%), high negative predictive value (84.6%), and acceptable overall diagnostic accuracy (75.4%). Its strong association with septic arthritis and ability to identify most infected cases support its utility as an effective screening tool, particularly in settings where immediate microbiological confirmation is unavailable.

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